

## Effect of side branch predilatation before provisional stenting in coronary bifurcation lesions

Effect of side branch predilatation

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### Abstract

**Aim:** Percutaneous coronary intervention (PCI) for bifurcation lesions remains technically challenging. Despite the development of single-stent provisional techniques and various dual-stent strategies, the problem of side branch (SB) occlusion and restenosis remains unresolved. In our study, we aimed to compare the side branch (SB) patency at the end of the procedure in patients with bifurcation lesions and significant SB disease, undergoing provisional stenting, with and without SB predilatation.

**Materials and Methods:** This retrospective observational study included 115 patients who underwent provisional PCI for true bifurcation lesions between January 2021 and November 2024. Patients were divided into two groups: those who received SB predilatation before provisional stenting and those who did not.

**Results:** The mean age of the 115 patients in our study was  $64.6 \pm 10.4$  years, and 31% were female. In the predilatation group, SB lesion severity, procedure duration, dissection rate, and kissing balloon requirement were significantly higher compared to the non-predilatation group ( $p < 0.05$ ).

**Discussion:** Our study showed that routine SB predilatation during provisional stenting of true bifurcation lesions is associated with higher rates of dissection and kissing balloon requirement. Similar to the literature, routine SB predilatation does not appear to be recommended. The use of NC balloons in predilatation may be beneficial, as it may reduce dissection rates. Large-scale studies with a high number of patients will be helpful in further elucidating these findings.

### Keywords

percutaneous coronary intervention, bifurcation lesions, coronary artery disease, side branch

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## Introduction

Coronary artery disease (CAD) is a major cause of mortality and morbidity worldwide [1]. In the invasive treatment of coronary artery disease, percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) surgery are commonly utilized [2]. Although PCI has become the standard treatment for CAD, PCI for bifurcation lesions remains technically challenging [3]. Despite the development of the provisional technique using a single stent and various two-stent strategies, the issue of side branch (SB) restenosis has not been fully resolved [4]. The two-stent approach may be required as the primary option in the most complex bifurcation lesions, in rare cases of difficult SB access, or long SB lesions [5]. In patients with an SB lesion length of <10 mm and an SB diameter of <2 mm, provisional stenting is generally preferred [6]. In such lesions, direct provisional stenting of the main branch may compromise SB flow, making rewiring of the SB challenging. This has led to the consideration of performing balloon predilatation of the SB before the procedure. However, according to the latest statements from the European Bifurcation Club, SB predilatation is generally not recommended [6]. The primary reason for this is that if dissection occurs in the SB following ballooning, rewiring the SB after provisional stenting of the main branch may become challenging [7]. A study on this topic suggests that SB predilatation is recommended, particularly in cases where there is a high risk of SB occlusion after main branch stenting, such as long ostial SB lesions or lesions with severe calcification [8]. In another study comparing the long-term mortality of patients who underwent HD predilatation with those who did not, it was found that the mortality of patients who underwent HD predilatation was higher [8]. However, the type of balloon used in these studies was not specified. As a result, there is insufficient data in the literature to establish a clear consensus on SB predilatation. In our study, we aimed to compare the post-procedural SB patency in patients with bifurcation lesions and significant SB disease who underwent provisional stenting, with or without SB predilatation.

## Materials and Methods

This retrospective observational study reviewed patients who underwent coronary angiography (CAG) between January 2021 and November 2024. Among these patients, those with true bifurcation lesions who underwent provisional stenting were included in the study. Patients who underwent direct two-stent bifurcation stenting, those with an SB diameter <2mm, those with an SB lesion length >10mm, those with isolated SB ostial lesions, patients with a life expectancy of less than one year, those with left main coronary artery stenosis, those with total occlusion in the relevant vessel, those with a left ventricular ejection fraction (LVEF) <30%, those with moderate or severe valvular heart disease, and patients with primary cardiomyopathy, as well as those with active cancer, active autoimmune diseases, active infections, end-stage liver failure, and chronic kidney disease requiring hemodialysis or peritoneal dialysis, were excluded from the study. The remaining 115 patients were selected as the final study cohort (Figure 1). This study was conducted in accordance with the Declaration of Helsinki.

The data to be evaluated will be obtained from the catheter laboratory archives of our hospital's cardiology department, patient files, and the hospital's computer record system. Blood samples were collected after an overnight fasting period following the procedure. Complete blood count (CBC) will be performed using the Coulter Counter LH Series by Beckman Coulter Inc., Hialeah, Florida, USA. Biochemical analyses were carried out by Roche Diagnostics, Mannheim, Germany, using a molecular analyzer.

The CAG images were reviewed, and the patients' SB diameters and the percentage of stenosis in the lesions were examined by two experienced interventional cardiologists. The patients with true bifurcation lesions who underwent provisional stenting were divided into two groups: those who underwent SB predilatation before the main branch stenting and those who did not. Semi-compliant (SC) and non-compliant (NC) balloons were used for SB predilatation. The study will evaluate whether there is a difference between the two groups in terms of procedural outcomes, including a decrease in flow velocity in the SB after main branch stenting, the development of dissection at the SB ostium, chest pain, electrocardiogram (ECG) changes during the procedure, the need for kissing balloon inflation, the need for SB stenting, and the procedural complications rate, considering all of these factors together. Additionally, demographic and blood parameter differences between the two groups will be assessed. Subgroups based on the type of balloon used will also be evaluated for similar procedural outcomes.

## Statistical analysis

Windows SPSS 21.0 (SPSS Inc., Chicago, Illinois, USA) was used for statistical analysis. Continuous variables were described as means  $\pm$  standard deviation or median (minimum, maximum), and categorical variables were expressed as number (percentage). Evaluations, including the Kolmogorov-Smirnov test, were performed to determine the normality of the distribution. Categorical variables were compared with the Chi-square or Fisher's exact test, and continuous variables were compared with the Mann-Whitney U test or Student t-test. Two-sided  $p < 0.05$  was considered statistically significant.

## Ethical Approval

Our study was approved by the Ethics Committee of Sivas Cumhuriyet University (Date:2025-01-16, No: 2025-01/36).

## Results

The mean age of the 115 patients in our study was  $64.6 \pm 10.4$  years, and 31% were female. The demographic and clinical data of the patients are listed in Table 1, with a comparison between the predilatation (+) and predilatation (-) groups. No significant difference was found between the two groups in terms of demographic and clinical characteristics. When examining angiographic characteristics, the predilatation group showed significantly higher lesion severity, procedure duration, dissection rate, and kissing balloon requirement compared to the non-predilatation group ( $p < 0.05$ ) (Table 1). In contrast, the non-predilatation group exhibited a significantly higher incidence of ECG changes during the procedure compared to the predilatation group ( $p < 0.05$ ) (Table 1). No significant differences were found between the two groups in terms of procedural complications. Laboratory data are presented in Table 1, with no significant

differences between the two groups. When comparing patients who underwent predilatation with only an NC balloon to the non-predilatation group in terms of angiographic parameters and procedural complications, no significant differences were found between the two groups (Table 2). When comparing patients who underwent predilatation with only an SC balloon to those who underwent predilatation with only an NC balloon, the rate of contrast-induced nephropathy was found to be significantly higher in the SC balloon group (38.1% vs. 0%;  $p = 0.011$ ). No significant differences were observed between the two groups in terms of other angiographic outcomes and procedural complications (Table 3).

Discussion

In our study, patients with true bifurcation lesions who underwent provisional PCI were compared between those who received SB ostium predilatation and those who did not. In the analysis, including all procedural complications, no significant difference was found between the two groups. However, the

procedure duration, dissection rate, and the need for kissing balloon inflation were significantly higher in the predilatation group compared to the non-predilatation group ( $p < 0.05$ ). No cardiovascular deaths were observed in either group. In the predilatation group, the severity of the SB ostium was found to be significantly higher (%80 vs. 50%,  $p < 0.001$ ). This suggests that operators tend to perform more predilatation as the severity of SB ostial lesions increases. In the recent study published by Carvalho et al., 143 out of 428 patients with true bifurcation lesions underwent SB predilatation, and their in-hospital and procedural outcomes were compared. Consistent with our findings, the proportion of SB lesions was significantly higher in patients who underwent predilatation compared to the other group. Additionally, in this study, the rate of conversion to a dual-stent strategy was higher in the predilatation group. Procedural complications and in-hospital events were similar between the two groups. ( available at: DOI: 10.1002/ccd.31465) In the treatment of bifurcation lesions, the proximal optimized (POT) provisional stenting technique forms the cornerstone

Table 1. Demographic, clinical, angiographic characteristics, and laboratory findings of patients

| Variables                         | Predilatation (+) (n=55) | Predilatation (-) (n=60) | p      |
|-----------------------------------|--------------------------|--------------------------|--------|
| Age, years                        | 65.0 ± 11.0              | 64.0 ± 10.0              | 0.613  |
| Females                           | 20 (36.4)                | 16 (26.7)                | 0.263  |
| DM                                | 23 (41.8)                | 23 (38.3)                | 0.703  |
| Hypertension                      | 37 (67.3)                | 35 (58.3)                | 0.322  |
| Tobacco                           | 21 (38.2)                | 24 (44.4)                | 0.507  |
| EF                                | 55.0 (30.0-65.0)         | 55.0 (30.0-65.0)         | 0.378  |
| The main artery to be operated on |                          |                          |        |
| LAD                               | 35 (63.6)                | 34 (56.7)                | 0.740  |
| CX                                | 15 (27.3)                | 20 (33.3)                |        |
| RCA                               | 5 (9.1)                  | 6 (10.0)                 |        |
| Side branch osteal lesion         | 80.0 (30.0-99.0)         | 50.0 (30.0-95.0)         | <0.001 |
| Main branch osteal lesion         | 95.0 (70.0-100.0)        | 90.0 (70.0-100.0)        | 0.459  |
| Processing time, minutes          | 50.0 (30.0-130.0)        | 40.0 (30.0-70.0)         | 0.018  |
| Heparin dose, U                   | 10000 (7000-10000)       | 10000 (7000-10000)       | 0.130  |
| Dissection                        | 14 (25.5)                | 1 (1.7)                  | <0.001 |
| TIMI flow score <3                | 18 (32.7)                | 9 (15.0)                 | 0.250  |
| Chest pain                        | 8 (14.5)                 | 3 (5.0)                  | 0.082  |
| ECG change                        | 4 (7.3)                  | 12 (20.0)                | 0.049  |
| Kissing balloon use               | 22 (40.7)                | 11 (18.3)                | 0.008  |
| Opaque nephropathy                | 16 (29.6)                | 11 (19.0)                | 0.187  |
| Antiaggregant used                |                          |                          |        |
| Clopidogrel                       | 47 (85.5)                | 47 (78.3)                | 0.323  |
| Ticagrelor                        | 8 (14.5)                 | 11 (18.3)                |        |
| Prasugrel                         | 0 (0.0)                  | 2 (3.3)                  |        |
| Procedural complications          | 32 (58.2)                | 28 (46.7)                | 0.217  |
| Hemoglobin, g/dl                  | 15.8 ± 1.7               | 13.5 ± 1.9               | 0.364  |
| Platelet count, x109/L            | 229.0 ± 56.0             | 251.0 ± 133.0            | 0.270  |
| Creatinine, mg/dl                 | 0.9 (0.5-1.5)            | 0.80 (0.5- 2.0)          | 0.478  |
| HDL-C, mg/dl                      | 38.0 (20.0-67.0)         | 36.0 (15.0-60.0)         | 0.166  |
| LDL-C, mg/dl                      | 109.0 (55.0-182.0)       | 110.0 (11.0-293.0)       | 0.929  |
| Triglycerides, mg/dl              | 128.0 (37.0-554.0)       | 102.0 (34.0-439.0)       | 0.329  |
| Total cholesterol, mg/dl          | 169.0 (95.0-255.0)       | 163.0 (59.0-335.0)       | 0.323  |
| C-reactive protein, mg/L          | 4.0 (1.0-108.0)          | 5.0 (1.0 -58.0)          | 0.567  |

Data are shown as mean ± standard deviation, number (%), or median (minimum, maximum)  
DM, Diabetes mellitus; EF, Ejection fraction; LAD, Left anterior descending artery; CX, Circumflex artery; RCA, Right coronary artery; TIMI, Thrombolysis in myocardial infarction ECG, Electro-cardiogram; HDL-C, High-density lipoprotein cholesterol; LDL-C, Low-density lipoprotein cholesterol; CRP, C-reactive protein;  $p < 0.05$  shows statistical significance

of our current approach to coronary bifurcation interventions [9,10]. In this technique, the potential loss of the SB and the subsequent challenges in rewiring the SB compel operators to seek solutions [6,7,10]. The main reason for this is thought to be the possibility of problems in YD rewiring due to possible

**Table 2.** Procedural comparison between patients who underwent predilatation with an nc balloon and those who did not undergo predilatation at all

| Variables                | Predilatation<br>(Only NC) (n = 12) | No Predilatation<br>(n = 60) | P     |
|--------------------------|-------------------------------------|------------------------------|-------|
| Dissection               | 2 (16.7)                            | 1 (1.7)                      | 0.070 |
| TIMI flow score <3       | 3. (25.0)                           | 9 (15.0)                     | 0.408 |
| Chest pain               | 3 (25.0)                            | 3 (5.0)                      | 0.054 |
| ECG change               | 1 (8.3)                             | 12 (20.0)                    | 0.681 |
| Kissing balloon use      | 4 (36.4)                            | 11 (18.3)                    | 0.228 |
| Opaque nephropathy       | 0 (0.0)                             | 11 (19.0)                    | 0.191 |
| Procedural complications | 5 (42.7)                            | 28 (46.7)                    | 0.751 |

Data are shown as a number (%)  
TIMI, Thrombolysis in myocardial infarction; ECG, Electrocardiogram; MACE, Major adverse cardiac events; p < 0.05 shows statistical significance

**Table 3.** Procedural comparison between patients who underwent nc balloon predilatation and patients who underwent sc balloon predilatation

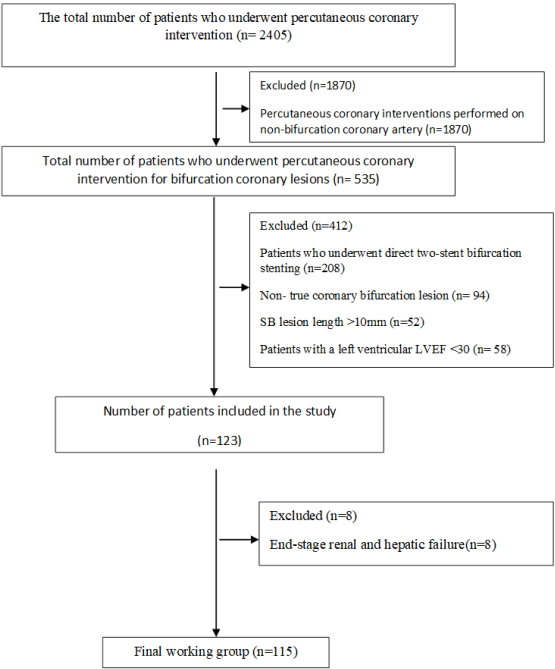
| Variables                | Predilatation<br>(Only NC) (n = 12) | Predilatation<br>(Only SC) (n = 43) | P     |
|--------------------------|-------------------------------------|-------------------------------------|-------|
| Dissection               | 2 (16.7)                            | 12 (27.9)                           | 0.709 |
| TIMI flow score <3       | 3 (25.0)                            | 15 (4.9)                            | 0.731 |
| Chest pain               | 3 (25.0)                            | 5 (11.6)                            | 0.352 |
| ECG change               | 1 (8.3)                             | 3 (7.0)                             | 1.000 |
| Kissing balloon use      | 4 (36.4)                            | 18 (41.9)                           | 1.000 |
| Opaque nephropathy       | 0 (0.0)                             | 16 (38.1)                           | 0.011 |
| Procedural complications | 5 (41.7)                            | 27 (62.8)                           | 0.190 |

Data are shown as a number (%)  
TIMI, Thrombolysis in myocardial infarction; ECG, Electrocardiogram; p < 0.05 shows statistical significance

dissections [11]. In the studies conducted, a higher rate of SB crossover stenting was observed in patients who underwent SB predilatation [12,13]. In line with the results of our study, patients who underwent SB predilatation exhibited a higher incidence of dissection, consistent with the literature. As a consequence, flow loss and the need for kissing balloon inflation were significantly higher in the predilatation group. In the first study conducted on this topic, the COBIS registry, 837 patients were included, with 175 patients undergoing predilatation. In the predilatation group, a significantly higher number of patients underwent rescue two-stent placement and kissing balloon inflation. Additionally, in this study, after 21 months of follow-up, the target vessel revascularization (TVR) rate was higher in the predilatation group [14]. In our study, similar to the aforementioned study, a higher incidence of SB ostium dissection and the need for kissing balloon inflation was observed. However, when comparing the group that underwent predilatation with only an NC balloon to the non-predilatation group, no significant difference was found in terms of dissection, kissing balloon need, or overall procedural complications. Additionally, when comparing patients who underwent predilatation with an NC balloon to those who received an SC balloon, although the dissection rate was numerically lower in the NC group, no significant difference was found between the two groups. Contrast-induced nephropathy was found to be significantly less common in the NC predilatation group compared to the SC predilatation group (p < 0.05). A likely reason for this could be that, due to fewer complications in the NC balloon group, the procedures were completed more quickly with less contrast use. Based on these results, it suggests that NC balloon predilatation may be associated with improved procedural success and a reduction in SB flow loss. We believe that further studies with larger patient populations could be beneficial. In the study by Vassilev et al., 324 out of 831 patients who underwent bifurcation PCI received predilatation, and long-term mortality was followed. While angiographic outcomes were significantly better in the predilatation group, the 8-year follow-up revealed a worse patient survival rate [15]. The association of these studies with long-term SB restenosis and TVR suggests that balloon dilation alone does not prevent lesion recoil over an extended period. Therefore, studies involving drug-coated balloons for SB predilatation could provide clearer data on this matter. Although our study does not include long-term mortality data, no in-hospital mortality was observed in any of the patients.

Limitation

The study is designed retrospectively. It is not blinded to the operator or the patient. Whether the operators perform balloon predilatation or not, and the type of balloon they use, depends on the operator, which makes the study subjective and susceptible to some degree of bias. Additionally, the inclusion of both elective and emergency PCI patients in the study population is an important limitation, as this may affect the results, and it is difficult to correlate these outcomes separately with clinical conditions. The sample size of the study is limited, and it was conducted at a single center. This may restrict the generalizability of the results. In the future, multicenter studies with larger sample sizes would be beneficial to validate the applicability of the results to a broader patient population.



**Figure 1.** Flowchart of the study

## Conclusion

In conclusion, in our study of provisional stenting for true bifurcation lesions, routine YD predilatation was associated with a higher incidence of dissection and the need for kissing balloon. Similar to the literature, it seems more reasonable not to apply routine predilatation. In patients who require predilatation, the use of NC balloons may be beneficial as it could reduce the incidence of dissection. Further studies with a larger patient sample would be valuable in this regard.

## Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

## Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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## Conflict of Interest

The authors declare that there is no conflict of interest.

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